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Docket No. ALI-T1011D1
Serial No. 10/643,298Remarks

Claims 1-3, 5-9 and 11-15 were pending in the subject patent application. By this amendment, claims 1, 3, 6, 9, 12, and 14 have been amended and claims 5 and 11 have been cancelled. No new matter has been added by this Amendment. Accordingly, claims 1-3, 6-9 and 12-15 remain before the Examiner for consideration.

The amendments set forth herein should not be taken to indicate the applicant's agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 3, 5, 9, and 11 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. In accordance with the Examiner's observations, and in order to expedite prosecution the applicant has amended the claims herein such that the phrase "per serving" has been removed from each of these claims and replaced with "per dosage." Support for this amendment can be found throughout the specification, including Table 1 on page 9 and Example 1 on page 15. Furthermore, in order to expedite prosecution, the applicant has now cancelled claims 5 and 11 thereby rendering moot the rejection of these claims. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection of claims 3, 5, 9, and 11 under 35 U.S.C. §112, first paragraph.

Claims 1-3, 5-9, and 11-15 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although the applicant respectfully believes that there is nothing ambiguous about the claims as previously presented, claims 1, 6, and 12 have been amended herein to clarify that the composition of the present invention may comprise additional ingredients but no amino acids except those that are explicitly listed as being part of the amino acid component. Additionally, the term "essential amino acid component" has been removed from the claims and replaced by "amino acid component." The applicant believes that the claims, as amended, distinctly point out the invention and respectfully requests withdrawal of this rejection.

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Claim 15 has been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 14 has been amended herein to correct the typographical error so that it now refers to the "immune system stimulator." There is now sufficient antecedent basis for the recitation of "stimulator" in claim 15. The applicant thanks the Examiner for her careful review of the claims and respectfully requests withdrawal of this rejection.

Claims 1, 6, and 7 have been rejected under 35 U.S.C. §102(b) as being anticipated by Winitz (U.S. Patent No. 3,697,287). The applicant respectfully traverses this ground of rejection to the extent that it might be applied to the current claims because the cited reference does not disclose the applicant's unique composition.

It is basic premise of patent law that, in order to anticipate, a single prior art reference must disclose within its four corners, each and every element of the claimed invention. In *Lindemann v. American Hoist and Derrick Co.*, 221 USPQ 481 (Fed. Cir. 1984), the court stated:

Anticipation requires the presence in a single prior art reference, disclosure of each and every element of the claimed invention, arranged as in the claim. *Connell v. Sears Roebuck and Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983); *SSII Equip. S.A. v. USITC*, 718 F.2d 365, 216 USPQ 678 (Fed. Cir. 1983). In deciding the issue of anticipation, the [examiner] must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference. *SSII, supra*; *Kalman [v. Kimberly-Clarke]*, 713 F.2d 760, 218 USPQ 781 (Fed. Cir. 1983)] (emphasis added). 221 USPQ at 485.

Please note that, unlike the Winitz composition, the amino acid component of the composition of the current invention consists only of arginine, leucine, isoleucine and valine. By contrast, the Winitz reference discloses compositions with many additional amino acids. The inclusion of these additional amino acids is explicitly prohibited by the claims as amended. Thus, Winitz does not disclose within its four corners all of the elements of the claimed invention. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b).

Claims 1-3 and 5 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Winitz (U.S. Patent No. 3,697,287) in view of Durst (U.S. Patent No. 3,434,843) and Millman

(U.S. Patent No. 4,871,550). The applicant respectfully traverses this ground for rejection to the extent that it might be applied to the claims now presented for examination.

The applicant understands that this rejection is based on the Examiner's interpretation of the previous claim language as permitting the presence of other amino acids. As noted above, the claims are now limited to the presence of only the four recited amino acids.

The shortcomings of the Winitz reference with respect to the current invention have been discussed above. The secondary Durst and Millman references do not cure these deficiencies. Specifically, the cited references disclose compositions with many additional amino acids. There is no mention or suggestion in any of the cited references to use the advantageous composition of the present invention having only the four specific amino acids.

The applicant respectfully submits that the cited references, even when combined, do not disclose or suggest, or provide any motivation to arrive at, the applicant's unique muscle-stimulating composition having only the specifically selected and identified amino acids. Accordingly, the applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. §103 based on Winitz in combination with Durst and Millman.

Claims 6-9 and 11-15 remain rejected under 35 U.S.C. §103(a) as being unpatentable over Rudman *et al.* (Growth hormone Treatment of Frailty in Men over 60, *New England Journal of Medicine*, 1990); Dudrick *et al.* (U.S. Patent No. 5,026,721) and Boynton *et al.* (U.S. Patent No. 5,087,624). The applicant respectfully traverses this ground for rejection because the cited references, alone or in combination, do not disclose or suggest the use of the applicant's specific composition to stimulate muscle growth or enhance immunity.

Surprisingly, the current inventor has found that a composition with only four specific amino acids is highly effective in promoting muscle growth. This particular formulation is quite unexpected because, for example, it does not include lysine and, at the time of the invention, those skilled in the art believed that arginine should be combined with lysine.

Specifically, a noted disadvantage associated with L-arginine is that when administered on its own, arginine tends to promote herpes 1 and 2, which gives rise, amongst other adverse effects, to mouth sores and genital discomfort. It is known that L-lysine inhibits the growth of

such viruses, and so lysine is conventionally administered with arginine to minimize the onset of herpes.

It has been discovered, surprisingly, according to the present invention that it is possible to administer L-arginine in the present composition with only three other amino acids, and without lysine. This is contrary to the conventional wisdom that existed at the time of the present invention. The claims now presented in this application exclude the presence of lysine.

It has been well established in the patent law that the mere fact that the purported prior art could have been modified or applied in some manner to yield applicant's invention does not make the modification or application obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 221 USPQ 1125,1127 (Fed. Cir. 1984). However, as expressed by the CAFC, to support a §103 rejection, "[b]oth the suggestion and the expectation of success must be founded in the prior art ..." *In re Dow Chemical Co.* 5 USPQ 2d 1529, 1531 (Fed. Cir. 1988). One finds neither the suggestion nor the expectation of success in the cited references, either separately or combined. An assertion of obviousness without the required suggestion or expectation of success in the prior art is tantamount to using applicant's disclosure to reconstruct the prior art to arrive at the subject invention. Hindsight reconstruction of the prior art cannot support a §103 rejection, as was specifically recognized by the CCPA in *In re Spinnoble*, 56CCPA 823, 160 USPQ 237, 243 (1969).

The Examiner asserts on page 15 of the October 4, 2006 Office Action that the fact that lysine was known be used with arginine to inhibit the growth of herpes viruses does not constitute a teaching away of a non-preferred embodiment of the present invention. However, a skilled artisan at the time of the current invention would have had no motivation to create a composition with arginine that did not include lysine. Due to the severity of herpes viruses, a person skilled in the art would have made sure to take precautions that were thought to be necessary to prevent the viruses. Thus, one skilled in the art would not have found the necessary motivation to combine any of the cited references to arrive at the applicant's invention.

The references to Dudrick *et al.* and Boynton *et al.* do not cure the deficiencies of the primary Pearson *et al.* (Rudman) reference. For example, Dudrick *et al.* provide an amino acid supplement comprising, as "primary" amino acids, arginine, leucine, valine and lysine (column

2, lines 48-50). Thus, if anything, Dudrick *et al.* teach away from the current invention. Boynton does not address this issue at all.

The Millnan and Winitz references (discussed above) also include lysine in addition to arginine. In light of the above teachings, it is clear that a person of ordinary skill, given the combination of Rudman *et al.*, Dudrick *et al.* and Boynton, would have been motivated at the date of the present invention to include L-lysine with L-arginine. In the present invention, lysine is specifically excluded.

The applicant further respectfully submits that there is no disclosure in Rudman *et al.* (or the other references) suggesting the combined use of leucine, isoleucine and valine.

The applicant respectfully submits that there is nothing in the cited art which would motivate the skilled artisan to produce the specific, unique and advantageous composition as currently claimed. Accordingly, in view of the foregoing remarks, reconsideration and withdrawal of the rejection under 35 U.S.C., 103 based on the cited references is respectfully requested.

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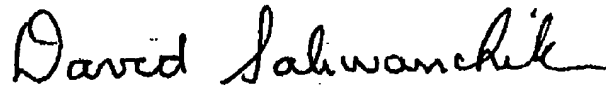
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In view of the foregoing remarks and the amendments above, the applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR 1.16 or 1.17 as required by this paper to Deposit Account 19-0065.

The applicant also invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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